#### REMARKS

#### I. The rejection under 35 U.S.C. § 103(a) should be withdrawn.

The Examiner rejected claims 1 and 5-11 as assertedly being unpatentable over Murad (U.S. Patent No. 6,800,292) in view of Norton (U.S. Patent No. 5,976,556). Applicant requests reconsideration of the rejection in view of the following remarks.

Independent claim 1 recites an external preparation (i.e., composition) comprising glycolic acid and polyethylene glycol (PEG), wherein the PEG has a polymerization degree of 2,000 to 50,000. Independent claim 6 recites an external preparation (i.e., composition) comprising glycolic acid and polyvinyl alcohol.

Murad simply does not disclose or suggest the preparations (i.e., compositions) recited in the claims as asserted by the Examiner. Murad discloses that its composition(s) comprise(s) at least one fruit extract<sup>1</sup> and a moisturizing agent. With respect to claim 1, Murad fails to disclose or suggest a composition comprising glycolic acid and polyethylene glycol (PEG), wherein the PEG has a polymerization degree of 2,000 to 50,000. Murad generically discloses that its compositions may contain PEG and specifically discloses PEG-100, which is clearly outside of the range recited in claim 1 (i.e., PEG-2,000 - PEG-50,000). Norton fails to remedy the deficiencies of Murad and generically discloses that its compositions may comprise ethylene glycol and specifically discloses PEG-40 and PEG-75. Norton is silent with respect to a composition comprising PEG with a polymerization degree of 2,000 to 50,000 and therefore cannot make up for the deficiencies of Murad.

The Examiner asserts that "a polymerization degree of from 2,000 to 50,000 is obvious of any polyethylene glycol in the preparation." However, the Examiner has not pointed to how the PEG recited in the claims is obvious in view of the cited art (which disclose PEG-40, PEG-75 and PEG-100). According to M.P.E.P. § 2141,

[w]hen making an obviousness rejection, Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. In certain circumstances, it may also be important to include explicit findings as to how a person of ordinary skill would have understood prior art teachings, or what a person of ordinary skill would have known or could have done. Factual findings made by Office personnel are the necessary underpinnings to establish obviousness.

<sup>&</sup>lt;sup>1</sup> The claims of the present invention do not require a fruit extract.

One of skill in the art would not have been motivated upon review of Murad and Norton to discard the PEG disclosed therein for the PEG recited in independent claim 1. First, PEG-40, PEG-75 and PEG-100 have degrees of polymerization of 40, 75 and 100, respectively, which is much lower than the range provided in claim 1. Second, it is known in the art that PEGs with varying degrees of polymerization have different functions. For example, PEG having a degree of polymerization below 100 functions as a humectant and/or a solvent while a PEG having a degree of polymerization 2,000 or greater functions as an emulsion stabilizer and/or a viscosity increasing agent. See, ICID and Handbook, 11<sup>th</sup> Edition (2006), pages 1549-1635 set forth in Appendix A. Finally, it is also known in the art that PEGs with varying degrees of polymerization are provided in different forms. For example, PEG having a degree of polymerization less than 420 is provided as a liquid, while PEG having a degree of polymerization greater than 570 is provided in a solid form. See, Aldrich Handbook of Fine Chemicals (2007-2008), page 2023 set forth in Appendix B. The Examiner has neither pointed to a specific teaching in the cited art nor provided findings of fact concerning the state of the art that would motivate one of skill in the art to replace a PEG provided in a liquid form for use as a humectant and/or solvent, such as the PEG-40, -75 or -100 disclosed in Norton or Murad, for a PEG provided in a solid form for use as an emulsion stabilizer and/or viscosity increasing agent, such as the PEG-2000 or greater disclosed in the present application.

The Examiner also failed to identify why one of skill in the art would be motivated to replace the PEG-100 of Murad or the PEG-40 or PEG-75 of Norton for the PEG recited in claim 1. In fact, attached as Appendix C is further experimental data indicating that a composition comprising a PEG having a degree of polymerization outside the range recited in claim 1 is inferior to the external preparation recited in claim 1. The results indicated that three different compositions comprising varying degrees of polymerization of PEG within the range recited in claim 1 (i.e., PEG-2000, PEG-7000 and PEG-45000) were more effective that a composition comprising PEG comprising a degree of polymerization well below the range recited in claim 1 (i.e., PEG-400).

Turning now to the rejection of independent claim 6, Applicant disagrees with the Examiner's conclusion that the combined teachings of the cited art render this claim and those claims dependent thereon obvious. The Examiner has not pointed to a teaching in Murad or Norton that discloses or suggests a specific composition comprising glycolic acid

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and polyvinyl alcohol. For example, Murad discloses that its composition comprises at least one fruit extract and a mono- or poly-hydroxy acid. Murad discloses that its composition comprises a mono- or poly-hydroxy acid selected from at least eighty (80) acids mono- or poly-hydroxy acids (col. 9, line 36 through col. 10, line 11) and a pharmaceutically acceptable carrier<sup>2</sup>, but does not specifically disclose a composition that comprises glycolic acid and polyvinyl alcohol.

Norton discloses that its composition comprises an acid protease<sup>3</sup> and an acidic buffer. Norton discloses that the acidic buffer includes one of at least twelve (12) acids (col. 10, lines 41-44) and one of at least nine (9) pharmaceutically acceptable carriers (col. 10, lines 63-65), but does not specifically disclose a composition that specifically comprises glycolic acid and polyvinyl alcohol. Accordingly, the combined teachings of Murad and Norton fail to teach or suggest the external preparation recited in claim 1.

In view of the foregoing, Applicant respectfully submits that the cited art fails to disclose or suggest the specific preparations recited in the claims. Accordingly, there is no *prima facie* case of obviousness and the rejection of claims 1 and 5-11 under 35 U.S.C. § 103(a) should be withdrawn.

#### II. Conclusion

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Dated: March 28, 2008

Respectfully submitted,

Electronic signature: /Jeanne M. Brashear/56,301 Jeanne M. Brashear Registration No.: 56,301 MARSHALL, GERSTEIN & BORUN LLP

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Agent for Applicant

<sup>&</sup>lt;sup>2</sup> Polyvinyl alcohol is listed as one of the more than seventy (70) pharmaceutically-acceptable carriers disclosed in Murad (col. 8, lines 40-66)

The claims of the present invention do not require an acid protease.

APPENDIX A

Docket No.: 19036/40139

# International Cosmetic Ingredient Dictionary and Handbook

Eleventh Edition 2006

Volume 2

INCI Name Monographs I-S

19

## International Cosmetic Ingredient Dictionary and Handbook

Eleventh Edition 2006

**Editors** 

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Volume 2

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Renex PEG 1000 (Uniqema Americas)
Sabopeg 1000 (Sabo)
Toho PEG#1000 (Toho)
Unipeg-1000 X (Universal Preserv-A-Chem)
Uplwax 1000 (Universal Preserv-A-Chem)
Trade Name Mixtures:
Silwax WS (Sittech LLC)

Silwax WS (Siltech LLC)
Suncaps 664 (Particle Sciences)
Suncaps 903 (Particle Sciences)

PEG-32

CTFA Monograph ID: 1955 CAS No.: 25322-68-3 (Generic)

JPN Translation: PEG-32 CN Translation: 聚乙二醇-32

**Defir** n: PEG-32 is the polymer of ethyle.... oxide that conforms generally to the formula:

H(OCH2CH2), OH

where n has an average value of 32.

Information Sources: BAN, BP, BPC, 21CFR172.210, 21CFR172.770, 21CFR172.820, 21CFR173.310, 21CFR173.340, 21CFR175.105, 21CFR175.300, 21CFR178.3750, 21CFR178.3910, CIR: [SQ] JACT-12(5)-1993, CTFA S, CZE, FCC, HUN, INN, JAN, JCIC, JCLS, JSQI, MAR, MI-13(7651), NF XVIII, TSCA, USAN, USD

Chemical Classes: Alkoxylated Alcohols; Polymeric Ethers

Functions: Binder; Humectant; Solvent

Ingredient Source: Synthetic

Reported Product Categories: Bath Oils, Table and Salts; Molsturizing Preparations; Cie. g Products (Cold Creams, Cleansing Lotions, Liquids and Pads); Bath Capsules; Skin Care Preparations, Misc.; Dentifrices (Aerosol, Liquid, Pastes and Powders); Bath Preparations, Misc.; Body and Hand Preparations (Excluding Shaving Preparations); Face and Neck Preparations (Excluding Shaving Preparations); Paste Masks (Mud Packs); Mascara

Technical/Other Names:

macrogol (INN) Polyethylene Glycol 1540 Polyoxyethylene (32) Trade Names:

Carbowax PEG 1450 (Dow Chemical) Jeechem 1450 NF (Jellice Co. LTD) Lipo Polyglycol 1500 (Lipo) Lipo Polyglycol 3350 (Lipo) Lipoxol 1500 MED (Sasol GmbH - Marl) Lumulse PEG 1450 (Lambent) Macrogol 1500 (NOF) Macrogol 1540 (NOF) Pluracare E 1500 (BASF) Pluracol E 1450 (BASF) Polyglycol E1450 (Dow Chemical) Polyglykol 1500 (Clarlant) Polyglykol 1500 (Clariant GmbH, Personal Care Protachem 1450 NF (Protameen) Renex PEG 1500 (Unigema Americas) Sabopeg 1500 (Sabo) Sympatens-PEG/1500 G (Kolb) Toho PEG#1540 (Toho)

Trade Name Mixtures:

Chem)

Carbowax PEG 540 Blend (Dow Chemical) Lanogen 1500 (Clariant) Lanogen 1500 (Clariant GmbH, Personal Care) Swertianin-P (Ichimaru Pharcos) Unipeg-1500 X (Universal Preserv-A-Chem) Uniwax 1450 (Universal Preserv-A-Chem)

Unipeg-1540 X (Universal Preserv-A-

**PEG-33** 

CTFA Monograph ID: 17410

**Definition:** PEG-33 is the polymer of ethylene oxide that conforms generally to the formula:

H(OCH2CH2),OH

where n has an average value of 33.

Chemical Classes: Alkoxylated Alcohols;

Polymeric Ethers

Functions: Binder; Humectant; Solvent

Ingredient Source: Synthetic Technical/Other Names: Polyethylene Glycol (33)

Polyoxyethylene (33)

Trade Name Mixtures:

SilSense Copolyol-1 Silicone (Noveon) SilSense Copolyol-7 Silicone (Noveon)

PEG-40

CTFA Monograph ID: 1956 CAS No.: 25322-68-3 (Generic)

JPN Translation: PEG-40 CN Translation: 窓乙二醇-40

**Definition:** PEG-40 is the polymer of ethylene oxide that conforms generally to the formula:

H(OCH2CH2),OH

where n has an average value of 40.

Information Sources: BAN, 21CFR172.210, 21CFR172.770, 21CFR172.820, 21CFR173.310, 21CFR173.340, 21CFR175.105, 21CFR175.300, 21CFR176.200, 21CFR178.3750, 21CFR178.3910, INN, JAN, JCIC, JCLS, MI-13(7651), NF XVIII, ROM, TSCA, USAN

Chemical Classes: Alkoxylated Alcohols;

Polymeric Ethers

Functions: Binder; Humectant; Solvent

Ingredient Source: Synthetic Technical/Other Names: macrogol (INN)

Polyethylene Glycol (2000) Polyoxyethylene (40)

Trade Names:

Pluracol E 2000 (BASF)
Polyglykol 2000 (Clariant)
Polyglykol 2000 (Clariant GmbH, Personal Care)

PEG-45

CTFA Monograph ID: 11904

CAS No.: 25322-68-3 (Generic)

**Definition:** PEG-45 is the polymer of ethylene oxide that conforms generally to the formula:

H(OCH2CH2)nOH

where n has an average value of 45.

Information Source: INN

Chemical Classes: Alkoxylated Alcohols;

Polymeric Ethers

Functions: Binder; Humectant; Solvent

Ingredient Source: Synthetic Technical/Other Names: macrogol (INN) Polyethylene Glycol (45)

Toho PEG#2000 (Toho)

Polyoxyethylene (45)

Trade Name:

PEG-55

CTFA Monograph ID: 7532

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MEG-55 (Cont.)

CAS No.: 25322-68-3 (Generic)

**CN Translation:** 聚乙二酸-55

Definition: PEG-55 is the polymer of ethylene oxide that conforms generally to the formula:

H(OCH2CH2),OH

where n has an average value of 55.

Information Sources: BAN, INN, JAN, NF XVIII, USAN

Chemical Classes: Alkoxylated Alcohols;

Polymeric Ethers

Functions: Binder; Humectant; Solvent

Ingredient Source: Synthetic Technical/Other Names: macrogol (INN) Polyethylene Glycol (55)

Polyoxyethylene (55)

Trade Names:

Jeechem 3350 NF (Jellice Co. LTD) Renex PEG 3350 (Uniqema Americas)

PEG-60

CTFA Monograph ID: 5425 CAS No.: 25322-68-3 (Generic)

JPN Translation: PEG - 60 **CN Translation:** 聚乙二醇-60

Definition: PEG-60 is the polymer of ethylene oxide that conforms generally to the formula:

H(OCH2CH2), OH

where n has an average value of 60.

Information Sources: BAN, INN, JAN, MI-13(7651), NF XVIII, USAN

Chemical Classes: Alkoxylated Alcohols; Polymeric Ethers

Functions: Binder; Humectant; Solvent

Ingredient Source: Synthetic i

Technical/Other Names: macrogol (INN) Polyethylene Glycol 3000 Polyoxyethylene (60)

Trade Names:

Polyglykol 3000 (Clarlant) Polyglykol 3000 (Clariant GmbH, Personal Care)

**PEG-75** 

CTFA Monograph ID: 1957

CAS No.: 25322-68-3 (Generic)

JPN Translation: PEG-75

Definition: PEG-75 is the polymer of ethylene oxide that conforms generally to the formula:

H(OCH2CH2),OH

where n has an average value of 75.

Information Sources: BAN, BP, BPC, BRA, 21CFR172.210, 21CFR172.770, 21CFR172.820, 21CFR173.310. 21CFR173.340, 21CFR175.105, 21CFR175.300, 21CFR178.3750, 21CFR178.3910, CIR: [SQ] JACT-12(5)-1993, CTFA S, FCC, HUN, INN, JAN, JCLS, JSCI, MAR, MI-13(7651), NF XVIII, NFJ, PN, POL, ROM, TSCA, USAN, USD

Chemical Classes: Alkoxylated Alcohols; Polymeric Ethers

Functions: Binder; Humectant; Solvent

Ingredient Source: Synthetic

Reported Product Categories: Skin Care Preparations, Misc.; Paste Masks (Mud Packs); Bath Oils, Tablets, and Salts; Cleansing Products (Cold Creams, Cleansing Lotions, Liquids and Pads); Moisturizing Preparations

Technical/Other Names:

macrogol (INN) Polyethylene Glycol 4000 Polyoxyethylene (75)

Trade Names:

Carbowax PEG 3350 (Dow Chemical) Lipoxol 3350 MED (Sasol GmbH - Marl) Lumulse PEG 3350 (Lambent) Pluracare E 3400 (BASF) Pluracol E 4000 (BASF) Polyglykol 3350 (Clarlant) Polyglykol 3350 (Clariant GmbH, Personal Care) Protachem 75 (Protameen) Renex PEG 4000 (Uniqema Americas)

Sabopeg 4000 (Sabo) Sympatens-PEG/4000 G (Kolb)

Upiwax 3350 (Universal Preserv-A-Chem)

Trade Name Mixture:

Suncaps C (Particle Sciences)

**PEG-80** 

CTFA Monograph ID: 16469

CAS No.: 25322-68-3 (Generic)

Definition: PEG-80 is the polymer of ethylene oxide that conforms generally to the formula:

H(OCH2CH2), OH

where n has an average value of 80.

Information Source: INN

Chemical Classes: Alkoxylated Alcohols

Polymeric Ethers

Functions: Binder; Humectant; Solvent

Ingredient Source: Synthetic

Technical/Other Names:

macrogol (INN) Polyethylene Glycol (80) Polyethylene Glycol 4000 Polyoxyethylene (80)

Trade Name:

Protachem 400 (Protameen)

PEG-90

CTFA Monograph ID: 6966

CAS No.: 25322-68-3

JPN Translation: PEG-90 CN Translation:

聚乙二醇-90

Definition: PEG-90 is the polymer of ethylene oxide that conforms to the formula:

H(OCH2CH2)nOH

where n has an average value of 90.

Information Sources: BAN, INN, JAN, NF

XVIII. USAN

Chemical Classes: Alkoxylated Alcohols;

Polymeric Ethers

Functions: Binder; Humectant; Solvent

Ingredient Source: Synthetic Technical/Other Names:

macrogol (INN) Polyethylene Glycol (90) Polyoxyethylene (90)

Trade Names:

Lipoxol 4000 MED (Sasol GmbH - Marl) Macrogol 4000 (NOF) Pluracare E 4000 (BASF) Polyglycol E-4000 (Dow Chemical) Polyglykol 4000 (Clariant) Polyglykol 4000 (Clariant GmbH, Personal

Toho PEG #4000 (Toho) Unipeg-4000 X (Universal Preserv-A-Chem)

PEG-100

CTFA Monograph ID: 4098

CAS No.: 25322-68-3 (Generic)

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#### PEG-2 Laurate SE (Cont.)

Definition: PEG-2 Laurate SE is a selfemulsifying grade of PEG-2 Laurate (g.v.) that contains some sodium and/or potassium laurate.

Information Sources: CIR: [SQ] IJT-19 (SUPPL. 2)2000, JCLS

Chemical Class: Alkoxylated Carboxylic Acids

Function: Surfactant - Emulsifying Agent ingredient Sources: Plant; Synthetic

#### Technical/Other Names:

Diethylene Glycol Monolaurate Self-Emulsifying

Polyethylene Glycol 100 Monolaurate Self-Emulsifying

Polyoxyethylene (2) Monolaurate Self-Emulsifying

#### Trade Name:

Lipo DGLS (Lipo)

#### Trade Name Mixture:

Pegosperse 100 L (Lonza Inc./Lonza Ltd.)

#### PEG-6 LAURATE/TARTRATE

CTFA Monograph ID: 5910

#### **CN Translation:**

PEG-6 月桂酸酯/酒石酸酯

Definition: PEG-6 Laurate/Tartrate is the mixed ester of PEG-6 and lauric and tartaric acids that conforms generally to the formula:

where n has an average value of 6.

Chemical Class: Alkoxylated Carboxylic Adds

Function: Surfactant - Emulsifying Agent ingredient Sources: Plant; Synthetic

Technical/Other Name: PEG-6 Laurate/Tartarate

#### Trade Name:

Hydrophore 312 (Prod'Hyg)

#### PEG-180/LAURETH-50/TMMG COPOLYMER

CTFA Monograph ID: 12111

Definition: PEG-180/Laureth-50/TMMG Copolymer is a copolymer of PEG-180 (q.v.), a polyethylene glycol ether of lauryl alcohol with an average ethoxylation value of 50, and tetramethoxymethylglycouril monomers.

Chemical Class: Synthetic Polymers Function: Viscosity Increasing Agent -

Aqueous

Ingredient Sources: Plant; Synthetic

#### Trade Name:

Pure Thix 1450 (Sud-Chemie, Performance

Additives)

#### PEG-10/LAURYL DIMETHICONE CROSS-POLYMER

CTFA Monograph ID: 16203

#### JPN Translation:

(PEG-10/ラウリルジメチコン)ク ロスポリマー

Definition: PEG-10/Lauryl Dimethicone Crosspolymer is a copolymer of Lauryl Dimethicone (q.v.) crosslinked with dially

Chemical Classes: Siloxanes and Silanes; Synthetic Polymers

Functions: Surfactant - Suspending Agent; Viscosity Increasing Agent - Aqueous

Ingredient Sources: Plant; Synthetic

#### Trade Name Mixtures:

KSG-34 (Shin-Etsu Chemical Co.) KSG-340 (Shin-Etsu Chemical Co.)

#### PEG-15/LAURYL DIMETHICONE CROSS-POLYMER

CTFA Monograph ID: 16204

#### JPN Translation:

(PEG-15/ラウリルジメチコン)ク ロスポリマー

Definition: PEG-15/Lauryl Dimethicone Crosspolymer is a copolymer of Lauryl Dimethicone (q.v.) crosslinked with diallyt PEG-15.

Chemical Classes: Siloxanes and Silanes:

Synthetic Polymers

Function: Viscosity Increasing Agent -

ingredient Sources: Plant; Synthetic

#### Trade Name Mixtures:

KSG-31 (Shin-Etsu Chemical Co.) KSG-32 (Shin-Etsu Chemical Co.)

KSG-33 (Shin-Etsu Chemical Co.)

KSG-34 (Shin-Etsu Chemical Co.)

KSG-310 (Shin-Etsu Chemical Co.)

KSG-320 (Shin-Etsu Chemical Co.)

KSG-330 (Shin-Etsu Chemical Co.)

KSG-340 (Shin-Etsu Chemical Co.)

#### **PEG-8 LINOLEATE**

CTFA Monograph ID: 5452

#### **CN Translation:** PEG-8 亚油酸酯

#### **Empirical Formula:**

C34H64O1n

Definition: PEG-8 Linoleate is the polyethylene glycol ester of linoleic acid that conforms to the formula:

$$\begin{array}{c} {\rm CH_3(CH_2)_4CH} \\ || \\ {\rm CHCH_2CH} \\ || \\ || \\ {\rm CH(CH_2)_7C} - ({\rm OCH_2CH_2)_5OH} \end{array}$$

where n has an average value of 8.

Information Source: MI-13(7660)

Chemical Class: Alkoxylated Carboxylic

Acids

Function: Surfactant - Emulsifying Agent

Ingredient Sources: Plant; Synthetic

#### Technical/Other Names:

Polyethylene Glycol 400 Linoleate Polyoxyethylene (8) Linoleate

#### Trade Name Mixture:

Efevit S (Fabriquimica)

#### **PEG-8 LINOLENATE**

CTFA Monograph ID: 5453

CN Translation: PEG-8 亚麻酸酯

#### Empirical Formula:

C34H62O10

Definition: PEG-8 Linolenate is polyethylene glycol ester of linolenic acid that conforms to the formula:

where n has an average value of 8,

Information Source: MI-13(7660)

Chemical Class: Alkoxylated Carboxylic

Function: Surfactant - Emulsifying Agent ingredient Sources: Plant; Synthetic

#### Technical/Other Names:

Polyethylene Glycol 400 Linclenate Polyoxyethylene (8) Linolenate

#### **Trade Name Mixture:**

Efevit S (Fabriquimica)

PEG-2M

CTFA Monograph ID: 1961

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PEG-14M

CAS No.: 25322-68-3 (Generic)

JPN Translation: PEG - 2 M

CN Translation: 聚乙二醇-2M

**Definition:** PEG-2M is the polymer of ethylene oxide that conforms generally to the formula:

H(OCH2CH2)2OH

where n has an average value of 2000.

Information Sources: 21CFR172.770, 21CFR173.310, 21CFR175.300, 21CFR178.3910, INN, JSQI, MI-13(7651), NF XVIII, TSCA, USAN

Chemical Classes: Alkoxylated Alcohols; Polymeric Ethers

Functions: Binder; Emulsion Stabilizer; Viscosity Increasing Agent - Aqueous

Ingredient Source: Synthetic

Reported Product Category: Hair Condi-

tioners

Technical/Other Names:

macrogol (INN)
PEG-2000
Polyethylena Glyco

Polyethylene Glycol (2000) Polyoxyethylene (2000)

Trade Name:

Polyox WSR N-10 (Amerchol)

Trade Name Mixture:

Spectraveil AQ (Uniqema Europe)

PEG-5M

CTFA Monograph ID: 1962

CAS No.: 25322-68-3 (Generic)

JPN Translation: PEG-5 M

CN Translation: 聚乙二醇-5M

**Definition:** PEG-5M is the polymer of ethylene oxide that conforms generally to the

formula:

H(OCH2CH2)nOH

where n has an average value of 5000.

Information Sources: 21CFR172.770, 21CFR173.310, 21CFR175.300, 21CFR178.3910, INN, JSQI, MI-13(7651), NF XVIII. TSCA. USAN

Chemical Classes: Alkoxylated Alcohols; Polymeric Ethers

Functions: Binder; Emulsion Stabilizer; Viscosity Increasing Agent - Aqueous

Ingredient Source: Synthetic

Reported Product Categories: Shampoos (Non-coloring); Hair Conditioners

Technical/Other Names:

macrogol (INN) PEG-5000

Polyethylene Glycol (5000) Polyoxyethylene (5000)

Trade Names:

Polyox WSR N-80 (Amerchol) Rita PEO-1 (Rita)

PEG-7M

CTFA Monograph ID: 1963
CAS No.: 25322-68-3 (Generic)

JPN Translation: PEG-7M

CN Translation: 黎乙二醇-7M

**Definition:** PEG-7M is the polymer of ethylene oxide that conforms generally to the formula:

H(OCH2CH2),OH

where n has an average value of 7000.

Information Sources: 21CFR172.770, 21CFR173.310, 21CFR175.300, 21CFR178.3910, INN, JSQI, MI-13(7651), NF XVIII, TSCA, USAN

Chemical Classes: Alkoxylated Alcohols;

Polymeric Ethers

Functions: Binder; Emulsion Stabilizer; Viscosity Increasing Agent - Aqueous

Ingredient Source: Synthetic

Reported Product Category: Shampoos

(Non-coloring)

Technical/Other Names:

macrogol (INN)
PEG-7000

Polyethylene Glycol (7000) Polyoxyethylene (7000)

Trade Name:

Polyox WSR N-750 (Amerchol)

PEG-9M

CTFA Monograph ID: 3708

CAS No.: 25322-68-3 (Generic)

JPN Translation: PEG-9M

CN Translation:

聚乙二醇-9M

**Definition:** PEG-9M is the polymer of ethylene oxide that conforms generally to the formula:

H(OCH2CH2),OH

where n has an average value of 9000.

Information Sources: 21CFR172.770, 21CFR173.310, 21CFR175.300, 21CFR178.3910, INN, JSQI, MI-13(7651),

NF XVIII, USAN

Chemical Classes: Alkoxylated Alcohols; Polymeric Ethers

Functions: Binder; Emulsion Stabilizer; Viscosity Increasing Agent - Aqueous

Ingredient Source: Synthetic

Technical/Other Names:

macrogol (INN) PEG-9000

Palyethylene Glycol 9000

Polyoxyethylene (9000)

Trade Names:

Alkox E-30G (Meisel) Rita PEO-2 (Rita)

PEG-14M

CTFA Monograph ID: 1964

CAS No.: 25322-68-3 (Generic)

JPN Translation: PEG-14M

CN Translation: 聚乙二醇-14M

**Definition:** PEG-14M is the polymer of ethylene oxide that conforms generally to the

H(OCH2CH2),OH

where n has an average value of 14000.

Information Sources: 21CFR172.770, 21CFR173.310, 21CFR175.300, 21CFR178.3910, CIR: [SQ] JACT-12(5)-1993, INN, JSQI, MI-13(7651), NF XVIII, TSCA, USAN

**Chemical Classes:** Alkoxylated Alcohols; Polymeric Ethers

Functions: Binder; Emulsion Stabilizer; Viscosity Increasing Agent - Aqueous

Ingredient Source: Synthetic

Reported Product Categories: Shampoos (Non-coloring); Shaving Preparations, Misc.; Shaving Cream (Aerosol, Brushless and Lather); Bath Oils, Tablets, and Salts; Bath Soaps and Detergents; Cleansing Products (Cold Creams, Cleansing Lotions, Liquids and Pads)

The inclusion of any compound in the Dictionary and Hendbook does not indicate that use of that substance as a cosmetic ingredient compiles with the laws and regulations governing such use in the United States or any other country.



#### PEG-14M (Cont.)

Technical/Other Names:

macrogol (INN) PEG-14000

Polyethylene Glycol (14000) Polyoxyethylene (14000)

Trade Names:

Polyox WSR-205 (Amerchol) Polyox WSR N-3000 (Amerchol)

PEG-20M

CTFA Monograph ID: 1965

CAS No.: 25322-68-3 (Generic)

JPN Translation: PEG - 20 M

CN Translation: 聚乙二醇-20M

Definition: PEG-20M is the polymer of ethylene oxide that conforms generally to the

formula:

H(OCH2CH2)nOH

where n has an average value of 20000.

Information Sources: 21CFR172.770, 21CFR173.310, 21CFR175.300, 21CFR178.3910, CIR: [SQ] JACT-12(5)-1993, EP, INN, JSQI, MI-13(7651), NF XIX, TSCA, USAN

Chemical Classes: Alkoxylated Alcohols; Polymeric Ethers

Functions: Binder; Emulsion Stabilizer; Viscosity Increasing Agent - Aqueous

Ingredient Source: Synthetic

Technical/Other Names:

macrogol (INN) Macrogolum 20000 (EP) PEG-20000

Polyethylene Glycol 20000

Polyoxyethylene (20000)

Trade Name Mixture:

Vegeles SR (Laboratoires Serobiologiques)

PEG-23M

CTFA Monograph ID: 3709

CAS No.: 25322-68-3 (Generic)

JPN Translation: PEG-23M

**CN Translation:** 聚乙二醇-23M

Definition: PEG-23M is the polymer of ethylene oxide that conforms generally to the

formula:

 $H(OCH_2CH_2)_nOH$ 

where n has an average value of 23000.

Information Sources: 21CFR172.770.

21CFR173.310, 21CFR175.300, 21CFR178.3910, INN, JSQI, MI-13(7651),

NF XVIII, USAN

Chemical Classes: Alkoxylated Alcohols:

Polymeric Ethers

Functions: Binder; Emulsion Stabilizer; Viscosity Increasing Agent - Aqueous

Ingredient Source: Synthetic

Technical/Other Names:

macrogol (INN)

PEG-23000

Polyethylene Glycol (23000) Polyoxyethylene (23000)

Trade Names:

Polyox WSR N-12K (Amerchol)

Rita PEO-3 (Rita)

PEG-25M

CTFA Monograph ID: 6480

CAS No.: 25322-68-3 (Generic)

JPN Translation: PEG-25M

**CN Translation:** 

聚乙二醇-25M

Definition: PEG-25M is the polymer of ethylene oxide that conforms generally to the

H(OCH2CH2),OH

where n has a value of 25000

Information Sources: INN, JSQI

Chemical Classes: Alkoxylated Alcohols;

Polymeric Ethers

Functions: Binder; Emulsion Stabilizer;

Viscosity Increasing Agent - Aqueous

Ingredient Source: Synthetic

Technical/Other Names:

macrogol (INN) PEG-25000

Polyethylene Glycol (25000) Polyoxyethylene (25000)

PEG-45M

CTFA Monograph ID: 3710

CAS No.: 25322-68-3 (Generic)

JPN Translation:

PEG-45M

CN Translation: 聚乙二醇-45M

Definition: PEG-45M is the polymer of ethylene oxide that conforms generally to the formula:

H(OCH2CH2),OH

where n has an average value of 45000.

Information Sources: 21CFR172.770. 21CFR173.310, 21CFR175.300, 21CFR178.3910, INN, JSQI, MI-13(7651),

NF XVIII, USAN

Chemical Classes: Alkoxylated Alcohols:

Polymeric Ethers

Functions: Binder; Emulsion Stabilizer; Viscosity Increasing Agent - Aqueous

Ingredient Source: Synthetic

Reported Product Category: Shampoos

(Non-coloring)

Technical/Other Names:

macrogol (INN) PEG-45000

Polyethylene Glycol (45000)

Polyoxyethylene (45000) Trade Name:

Polyox WSR N-60K (Amerchol)

PEG-65M

CTFA Monograph ID: 15211

CAS No.: 25322-68-3 (Generic)

Definition: PEG-65M is the polymer of ethylene oxide that conforms generally to the

formula:

H(OCH2CH2),OH

where n has an average value of 65000.

Information Source: INN

Chemical Classes: Alkoxylated Alcohols;

Polymeric Ethers

Functions: Binder; Emulsion Stabilizer; Viscosity Increasing Agent - Aqueous

Ingredient Source: Synthetic

Technical/Other Names:

macrogol (INN)

Polyethylene Glycol (65000) Polyoxyethylene (65000)

Trade Name:

Alkox E-100 (Meisei)

PEG-90M

CTFA Monograph ID: 1966 CAS No.: 25322-68-3 (Generic)

JPN Translation: PEG - 90 M

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#### PEG-20 Mannitan Laurate

**CN** Translation: 聚乙二醇-90M

Definition: PEG-90M is the polymer of ethylene oxide that conforms generally to the formula:

H(OCH2CH2)nOH

where n has an average value of 90000.

Information Sources: 21CFR172.770, 21CFR173.310, 21CFR175.300, 21CFR178.3910, INN, JSQI, MI-13(7651),

NF XVIII, TSCA, USAN

Chemical Classes: Alkoxylated Alcohols; Polymeric Ethers

Functions: Binder; Emulsion Stabilizer; Viscosity Increasing Agent - Aqueous

Ingredient Source: Synthetic

Technical/Other Names:

macrogol (INN) PEG-90000

Polyethylene Glycol (90000) Polyoxyethylene (90000)

Trade Names:

Polyox WSR-301 (Amerchol) Rita PEO-18 (Rita)

PEG-115M

CTFA Monograph ID: 3711 CAS No.: 25322-68-3 (Generic)

JPN Translation: PEG-115M **CN Translation:** 

聚乙二醇-115M Definition: PEG-115M is the polymer of ethylene oxide that conforms generally to the

formula:

H(OCH2CH2)nOH

where n has an average value of 115000.

Information Sources: 21CFR172.770, 21CFR173.310, 21CFR175.300, 21CFR178.3910, INN, JSQI, MI-13(7651)

Chemical Classes: Alkoxylated Alcohols;

Polymeric Ethers

Functions: Binder; Emulsion Stabilizer; Viscosity Increasing Agent - Aqueous

Ingredient Source: Synthetic

Technical/Other Names:

macrogol (INN) PEG-115000 Polyethylene Glycol (115000) Polyoxyethylene (115000)

Trade Name:

Alkox E-240 (Meisei)

**PEG-160M** 

CTFA Monograph ID: 7730 CAS No.: 25322-68-3 (Generic)

JPN Translation:

PEG-160M CN Translation: 聚乙二醇-160M

Definition: PEG-160M is a polymer of ethylene oxide that conforms generally to the formula:

H(OCH2CH2),OH

where n has an average value of 160000.

Information Source: INN

Chemical Classes: Alkoxylated Alcohols;

Polymeric Ethers

Functions: Binder; Emulsion Stabilizer; Viscosity Increasing Agent - Aqueous

Ingredient Source: Synthetic

Technical/Other Names:

macrogol (INN) Polyethylene Glycol (160000) Polyoxyethylene (160000)

Trade Name:

Rita PEO-27 (Rita)

PEG-180M

CTFA Monograph ID: 18747 CAS No.: 25322-68-3 (Generic)

Definition: PEG-180M is the polymer of ethylene oxide that conforms generally to the

formula:

H(OCH2CH2)nOH

where n has an average value of 180,000.

Information Source: INN

Chemical Classes: Alkoxylated Alcohols;

Polymeric Ethers

Functions: Binder, Emulsion Stabilizer, Viscosity Increasing Agent - Aqueous

Ingredient Source: Synthetic

Technical/Other Names:

macrogol (INN)

Polyethylene Glycol 118000

Trade Name:

Polyox WSR-308 (Amerchol)

**PEG-16 MACADAMIA GLYCERIDES** 

CTFA Monograph ID: 12413

JPN Translation:

PEG-16マカデミアグリセリズ

Definition: PEG-16 Macadamia Glycerides is the polyethylene glycol derivative of the mono- and diglycerides derived from macadamia nut oll with an average of 16 moles of ethylene oxide.

Chemical Classes: Alkoxylated Alcohols; Glyceryl Esters and Derivatives

Functions: Skin-Conditioning Agent -Emollient; Surfactant - Emulsifying Agent

Ingredient Sources: Plant; Synthetic

Technical/Other Names:

Polyethylene Glycol (16) Macadamia

Glycerides

Polyoxyethylene (16) Macadamia Glycerides

Trade Name:

Florasolvs PEG-16 Macadamia (Floratech)

Trade Name Mixtures:

EiXtractives B (Essential Ingredients) EiXtractives CS (Essential Ingredients) EiXtractives DS (Essential Ingredients) EiXtractives EC (Essential Ingredients) Eixtractives HL (Essential Ingredients) EiXtractives OS (Essential Ingredients) VitaCon ABCM (Essential ingredients) VitaCon ACEM (Essential Ingredients) VitaCon ADEM (Essential Ingredients) VitaCon AEKM (Essential Ingredients) VitaCon AEM (Essential Ingredients)

VitaCon AM (Essential Ingredients)

**PEG-70 MANGO GLYCERIDES** 

CTFA Monograph ID: 6687

**CN Translation:** PEG-70 芒果甘油酯类

Definition: PEG-70 Mango Glycerides is a polyethylene glycol derivative of the mono-. and diglycerides from mango seed oil containing an average of 70 moles of ethylene oxide.

Chemical Classes: Alkoxylated Alcohols; Glyceryl Esters and Derivatives

Functions: Skin-Conditioning Agent -Emollient; Surfactant - Cleansing Agent; Surfactant - Solubilizing Agent

Ingredient Sources: Plant; Synthetic

Technical/Other Names:

Polyethylene Glycol (70) Mango Glycerides Polyoxyethylene (70) Mango Glycerides

Trade Name:

Lipex 203 E-70 (Karlshamns AB)

**PEG-20 MANNITAN LAURATE** 

CTFA Monograph ID: 7402

The inclusion of any compound in the Dictionary and Handbook does not indicate that use of that substance as a cosmetic ingredient complies with the laws and regulations governing such use in the United States or any other country.

#### APPENDIX B

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			\$
ylenedi	ioxythiophene)	, tetramethacryl	ete end-
nethacn	ylate end-capped ilfonate dopant	i	
	0.0	1-0.5 S/cm (bulk c	onductivity)
	as dopant	ne carbonate), co	ontains p-
1.1 <b>8</b> 9 132 °C	g/mL, 25 °C (270 °F) Moisture	sensitive	
	glass btl	25 g	<b>8</b> 5.80
fonate pin coat -6,000	sion in nitrome as dopant ting applications g/mL, 25 °C	rthane), contains	s p-
2 S: 41	Fp: 36 °C (97 °F)		
	glass btl	25 g	<b>8</b> 5.80
M-00-4	thyl acrylate)		
(CH <sub>2</sub> Cl	H <sub>2</sub> ) <sub>8</sub> [CH <sub>2</sub> CH(CO <sub>2</sub>	C2H5) v	
0.93	g/mL, 25 °C		
osity 0.7	late: 18 wt. %, 8 dL/g(lit.)		
st			
i	glass btl	500 g	<b>49</b> 10
	<b>late: 18 wt. %,</b> i1 dL/g(lit.)		
			152 °C
ì	glass btl	500 g	\$5.20
ne co-g	lycidyl methecr	ylete)	State Control
+0	CH <sub>2</sub> -CH <sub>2</sub> CH <sub>2</sub>	CH <sub>3</sub>	
] nt		°C (Vicat, ASTM D sity 0.94 g	-
t index	(190°C/2.16kg)		
	ngs and adhesion (STM D 2240) 93		

Poly(ethylene glyco	si)						
_					osity		
Form	Mol. Wt.		M.P. (°C)	at 21	0 °F (cSt)	Prod. No.	Price
liquid	average mol wt	200	-65		4.3	P3015-5G	9.00
						P3015-250G P3015-500G	12.90 21.50
						P3015-1KG	33.20
						P3015-20KG	531.00
viscous liquid	average M <sub>n</sub> 285	-315	-15-8		5.8	202371-5G	19.10
						202371-250G	21.50
						202371-500G 202371-1KG	23.80 36.50
						202371-1KG 202371-20KG	433.50
viscous liquid	average Mn 380-	-420	4-8		7.3	202398-5G	19.10
						202398-250G	23.40
						202398-500G 202398-20KG	43.30 432.50
waxy solid (moist)	average M <sub>o</sub> 570-	-630	20-25		10.5	202401-5G	19.10
VVOXY SONG (INDISE)	average Min 370	-030	20-23		10.5	202401-250G	26.00
						202401-500G	26.30
						202401-20KG	433.50
waxy solid	average M <sub>n</sub> 850-		32-36		16	372994	Inquire
waxy solid	average M <sub>n</sub> 950-1	1,050	39		17.4	P3515-5G	13.10
						P3515-250G P3515-500G	18.00 21.60
						P3515-1KG	32.40
waxy solid	average M <sub>o</sub> 1,305-	1,595	43-46		28	202436-5G	15.50
	•					202436-250G	22.80
						202436-500G	30.60
alata a						202436-20KG	382.00
chips	average M <sub>n</sub> 1,900-	2,200	52-54		•	295906-5G 295906-250G	20.10 24.20
						295906-500G	31.10
powder	average M <sub>n</sub> 3,015-	3,685	54-58		90	202444-5G	21.60
,	<b>3</b> ,					202444-250G	29.00
						202444-500G	33.60
flakes	average M <sub>n</sub> 4,400-	4,800	57-61		180	373001-10G	21.30
						373001-250G 373001-1KG	24.80 55.00
powder (crystalline)	average M <sub>n</sub> 7,000-	0.000	60-63		800	202452-5G	18.10
portaci (crystomic)	average min 7,000-	3,000	00-03		000	202452-36 202452-250G	27.40
						202452-500G	32.00
flakes	average Mn		63-65		-	309028-5G	18.70
	8,500-11,500	)				309028-250G	22.10
						309028-500G	26.10
waxy solid	average M <sub>n</sub> 140	000	62-67		-	637726-100G 637726-1KG	24.50 136.00
Poly(ethylene glycol	l) acrylate		, 444)	R: 20/21/22-3	4-43 S: 26-27	7-36/37/39-45 Fp: 113	3 °C (235 °F)
[9051-31-4] H <sub>2</sub> C=CH					ertage had	100 mil	30.50
density 1.12 g	√mL, 25 °C n <sub>D</sub>		1.466	468258-100ML 468258-250ML	glass btl	100 mL	29.50
average M <sub>n</sub> ~375 viscosity 42 cSt (25 °C	Vii+ \			****	glass btl	250 mL	60.20
contains 1,000-1,500		itor			-	uminopropyi) term	insted
	36 Fp: 113 °C (235 °F)					ylene glycol 1,500	
469823-100ML	glass btl	100 mL	31.30	[34901-14-9] (C			
	9	500 mL	103.50	S: 22-24/25 TSCA		C	
-	~	******		452572-1G	glass btl	1 g	26.60
Poly(ethylene glycol	•			452572-5G	glass btl	5 g	87.50
[125441-87-4] H <sub>Z</sub> C=			- 1	Poly(ethylene gi	ycol) bis(car	boxymethyl) ethe	r ay sigha
<b>average M<sub>n</sub> ~1,500,</b> Copolymerizable surfa					•	Polyglycol 600 diac	
iatexes.	com one associative	unckerie	i iii aciyiic	120027 00 71 116	DOCCH IOCI	LEUN OCH COOK	
viscosity 300 cP (25 °C	(lit.)			[39927-08-7] HC R: 34 S: 26-	36/37/39-45	Fp. 113 °C (235 °F)	
contains 1000 ppm N	MEHQ as stabilizer, 25	% water					
bn	95 °C n <sup>20</sup>		1.431	▶ average M <sub>n</sub> ~2	:DU		

thacrylate 8 wt. % 38 S: 26-36 TSCA

glass btl

glass bti

250 g

1 kg

23.90

49.50

bp .....density ......

406996-100G

glass btl 100 g

.. 1.454

73.90

#### APPENDIX C

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#### **Additional Data:**

Preparation of Test Compositions:

Composition B was prepared as described in Example 1 described in Table 1 of the application (see page 7 of the application). Composition B comprises polyethylene glycol (PEG) having a degree of polymerization of 45,000. Compositions A, B and D, were prepared as described above for Composition B, except that Composition A comprises polyethylene glycol (PEG) having a degree of polymerization of 7,000; Composition C comprises PEG having a degree of polymerization of 2,000 and Composition D comprises a PEG having a degree of polymerization of 400.

Evaluation of Application Performance and Effectiveness of the Tested Compositions:

Seven 5 cm<sup>2</sup> flamed areas were defined on the forearms of ten male subjects between the ages of twenty and forty. Compositions A-D were applied to the flamed areas with a flat brush. Application performance of the various compositions was evaluated and classified into one of two groups ("the composition was capable of being applied in a uniform manner" or "the composition, when applied, was liable to be uneven").

After ten minutes the test compositions were washed away with water. After twenty-four hours, the forearms of the subjects were visually examined and the effectiveness of each composition was determined by examining the stratum corneum (i.e., the top layer of skin) for uniform peeling. The effectiveness of each composition was classified into one of three group ("after application of the composition, the stratum cornuem was uniformly peeled," "after application of the composition, the stratum corneum was peel patchwise" and "after application of the composition, the stratum corneum was not peeled"). Results indicated that the compositions comprising PEG having a degree of polymerization between 2,000 and 50,000 (i.e., Compositions A-C) were more effective than the compositions comprising PEG having a degree of polymerization below 2,000 (i.e., Composition D). See Table A below.

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Evaluation of the Stability of the Tested Compositions:

The viscosity of Composition B on the next day was assumed to be 100. The viscosities of the other compositions on the next day are shown in Table A in a relative value.

Table A. Results.

	Degree of Polymerization	Viscosity on the next	Application Performance		Effectiveness		
		day	Capable of being applied in a uniform manner	Liable to be uneven	Stratum corneum was uniformly peeled	Stratum corneum was peeled patchwise	Stratum corneum was not peeled
Composition A	7,000	80	9	1	7	3	0
Composition B	45,000	100	9	1	8	2	0
Composition C	2,000	72	9	1	8	2	0
Composition D	400	Unable to evaluate (water-like)	2	8	2	8	0